K071446

510(k) SUMMARY

JUL - 2 2008

Submitted by:	Electrode Arrays 612 N. Resler El Paso, TX 79912 (915) 760-5253
Contact Person:	Elvira Garcia
Date Prepared:	May 22, 2007
Proprietary Name:	Electrode Array Cap
Common Name:	Electrode Positioning Cap
Classification Name:	Electrodc, Metallic with Soft Pad Covering
Predicate Device:	Electro-Cap 510(k) K780045 Quik-Cap 510(k) K000865

Description of the Device: The Electrode Array Cap comprises an electrode placement system for positioning electrodes. The density of electrodes will vary, but in general will conform to the 10-20 to 5-5 positioning system (Oostenveld & Praamstra, 2005). The electrode will be compatible with all standard AC/DC EEG amplifiers The Electrode Array Cap will consist of an elastic cap, electrode holders, sintered Ag/AgCl electrodes, and shielded wire lead wires. The Electrode Array Cap will fit all head shapes and sizes and will be comfortable to wear. Shielded wires will terminate into a standardized connector designed. Separate shielded cables, tailored to each amplifier system, will mate with the standardized cap connector. Located in each connector will be a passive memory chip that will read out the serial number and other device information.

Intended Use of the Device: The Electrode Array Cap has the same intended use as the predicate device and is intended for routine clinical settings where rapid placement of large numbers of EEG electrodes is desired.

Technological Characteristics: The Electrode Array Cap has the same technological characteristics as the predicate device. The design of the Electrode Array Cap is in conformance with AAMI Standard Specifications for ECG Cables and Leadwires and Other Devices that use Patient Cables, EC53-1995, and the IEC Standard 60601-1 subclause 56.3, (c). The Electrode Array Cap, like the predicate device, consists of a stretchable elastic fabric cap, sintered Ag/AgCl electrodes, in electrode holders and shielded lead wires. The perforations on the cap help in reducing heat on the subject's head. The electrode holder is a 2 part component made of a PVC material. The purpose for the PVC material is to allow the 2 parts to snap together between the fabric. Another characteristic of the Electrode Array Cap is the placement of the electrode lead wires are on thc inside of the cap. This allows the cap to slip more easily on the subject' head and gives the technician easy access to the electrodes without the interference of the lead wires.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Rockville MD 20850

Electrode Arrays
% Ms. Elvira Garcia
QA/RA Manager
612 North Resler Drive, Suite C
El Paso, Texas 79902

JUL - 2 2008

Re: K071446
Trade/Device Name: Electrode Arrays Cap
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: II
Product Code: GXY
Dated: April 4, 2008
Received: April 7, 2008

Dear Ms. Garcia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071446

Device Name: Electrode Arrays Cap

Indications For Use: The Electrode Arrays Cap is intended for routine clinical settings where rapid placement of large number or EEG electrodes is desired.

Prescription Use __XX__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071446